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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 09/988,292             | YU ET AL.           |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | Joyce Tung             | 1637                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/15/2003.
2. ☒ The allowed claim(s) is/are claims 19-88 (final claims 1-70).
3. ☒ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>10/3</u> . |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.              | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                         |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance        |
|  | 9 <input type="checkbox"/> Other _____   |

### EXAMINER'S AMENDMENT

Following entry the amendment filed 4/15/2003, the claims 19-88 are pending.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Lin J. Hymel on 10/30/2003.

2. The application has been amended as follows:

In claim 44, line 1, delete "CSG10", insert – the -- and after "protein", insert – of SEQ ID NO: 16 --; line 4, delete "CSG10", insert – present of the antibody or portion thereof bound to the – and after "protein", insert – of SEQ ID NO: 16 --.

In claim 80, line 1, delete "CSG10", insert – the -- and after "protein", insert – of SEQ ID NO: 16 --; line 4, delete "CSG10", insert -- present of the antibody or portion thereof bound to the – and after "protein", insert – of SEQ ID NO: 16 --.

3. Claims 19-43 and 53-79 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 44-52 and 80-88, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, now subject to being rejoined. Claims 44-52 and 80-88 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

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Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made 3/26/2002 is hereby withdrawn.

4. The following is an examiner's statement of reasons for allowance:

Concerning claims 19-43 and 53-79, no prior art has been found an isolated human, humanized, or chimeric antibody or portion thereof that specifically binds to a protein selected from the group consisting of: (a) a protein whose sequence consists of amino acid residues 1 to 323 of SEQ ID NO: 16; (b) a protein consisting of a fragment of SEQ ID NO: 16, wherein said fragment comprises at least 30 contiguous amino acid residues of SEQ ID NO: 16; and (c) a protein consisting of a fragment of SEQ ID NO: 16, wherein said fragment comprises at least 50 contiguous amino acid residues of SEQ ID NO: 16.

Concerning claims 44-52 and 80-88, no prior art has been found the method of detecting the protein of SEQ ID NO:16 in a biological sample with the antibody or portion thereof claim 19 or 53.

The closest prior art is the reference of Oda et al.. Oda et al. disclose that an antibody against RI-H were raised in rabbits (See pg. 5930, column 2, third paragraph). The amino acid sequence of RI-H comprises SEQ ID NO:16 as indicated in the search report (See pg. 5934, fig. 2 and the search report previously attached). Oda et al. do not disclose producing the human, humanized, or chimeric antibody or portion thereof against the protein of SEQ ID NO:16 used in the method to detect the protein of SEQ ID NO:16 in a biological sample.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


5. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung  
October 30, 2003

  
**ETHAN WHISENANT**  
**PRIMARY EXAMINER**

ALLOWED CLAIMS/ TJ

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**19. (Twice Amended) An isolated human, humanized, or chimeric antibody or portion thereof that specifically binds to a protein selected from the group consisting of:**

- (a) a protein whose sequence consists of amino acid residues 1 to 323 of SEQ ID NO:16;**
- (b) a protein consisting of a fragment of SEQ ID NO:16, wherein said fragment comprises at least 30 contiguous amino acid residues of SEQ ID NO:16; and**
- (c) a protein consisting of a fragment of SEQ ID NO:16, wherein said fragment comprises at least 50 contiguous amino acid residues of SEQ ID NO:16.**

20. The antibody or portion thereof of claim 19 that specifically binds protein (b).
21. The antibody or portion thereof of claim 19 that specifically binds protein (c).
22. The antibody or portion thereof of claim 19, wherein said protein specifically bound by said antibody or portion thereof is glycosylated.
23. The antibody or portion thereof of claim 19 which is a monoclonal antibody.
24. The antibody or portion thereof of claim 19 which is a polyclonal antibody.
25. The antibody or portion thereof of claim 19 which is a chimeric antibody.
26. The antibody or portion thereof of claim 19 which is a humanized antibody.
27. The antibody or portion thereof of claim 19 which is a human antibody.
28. The antibody or portion thereof of claim 19 which is a single chain antibody.
29. The antibody or portion thereof of claim 19 which is a Fab fragment.
30. The antibody or portion thereof of claim 19 which is labeled.

31. The antibody of claim 30, wherein the label is selected from the group consisting of:

- (a) an enzyme label;
- (b) a radioisotope; and
- (c) a fluorescent label:

32. A composition comprising the antibody or portion thereof of claim 19 and a carrier.

33. The composition of claim 32, wherein the antibody or portion thereof is a monoclonal antibody.

34. The composition of claim 32, wherein the antibody or portion thereof is a chimeric antibody.

35. The composition of claim 32, wherein the antibody or portion thereof is a humanized antibody.
36. The composition of claim 32, wherein the antibody or portion thereof is a human antibody.
37. The composition of claim 32, wherein the antibody or portion thereof is a single chain antibody.
38. The composition of claim 32, wherein the antibody or portion thereof is a Fab fragment.
39. The composition of claim 32, wherein the antibody or portion thereof is labeled.
40. The composition of claim 39, wherein the label is selected from the group consisting of:
- (a) an enzyme label;
  - (b) a radioisotope; and
  - (c) a fluorescent label.
41. An isolated cell that produces the antibody of claim 19.
42. A hybridoma that produces the antibody of claim 19.



43. A hybridoma that produces the antibody of claim 23.
44. A method of detecting CSG10 protein in a biological sample comprising:
  - (a) contacting the biological sample with the antibody or portion thereof of claim 19; and
  - (b) detecting the CSG10 protein in the biological sample.
45. The method of claim 44, wherein the antibody is a monoclonal antibody.
46. The method of claim 44, wherein the antibody is a polyclonal antibody.
47. The method of claim 44, wherein the antibody is a chimeric antibody.
48. The method of claim 44, wherein the antibody is a humanized antibody.
49. The method of claim 44, wherein the antibody is a human antibody.
50. The method of claim 44, wherein the antibody is a single chain antibody.
51. The method of claim 44, wherein the antibody is a labeled antibody.
52. The method of claim 51, wherein the label is selected from the group consisting of:
  - (a) an enzyme label;

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(b) a radioisotope; and

(c) a fluorescent label.

53. (Twice Amended) An isolated human, humanized, or chimeric antibody or portion thereof produced by immunizing an animal with a protein selected from the group consisting of:

(a) a protein whose sequence comprises amino acid residues 1 to 323 of SEQ ID NO:16;

(b) a protein whose sequence comprises at least 30 contiguous amino acid residues of SEQ ID NO:16; and

(c) a protein whose sequence comprises at least 50 contiguous amino acid residues of SEQ ID NO:16,

wherein said antibody or portion thereof specifically binds to the amino acid sequence of SEQ ID NO:16.

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54. The antibody or portion thereof of claim 53 produced by immunizing an animal with protein (a).

55. The antibody or portion thereof of claim 53 produced by immunizing an animal with protein (b).

56. The antibody or portion thereof of claim 53 produced by immunizing an animal with protein (c).

57. (Once Amended) The antibody or portion thereof of claim 19 that specifically binds protein (a).

58. The antibody or portion thereof of claim 57, wherein said protein specifically bound by said antibody or portion thereof is glycosylated.

59. The antibody or portion thereof of claim 57 which is a monoclonal antibody.

60. The antibody or portion thereof of claim 57 which is a polyclonal antibody.

61. The antibody or portion thereof of claim 57 which is a chimeric antibody.

62. The antibody or portion thereof of claim 57 which is a humanized antibody.

63. The antibody or portion thereof of claim 57 which is a human antibody.

64. The antibody or portion thereof of claim 57 which is a single chain antibody.

65. The antibody or portion thereof of claim 57 which is a Fab fragment.

66. The antibody or portion thereof of claim 57 which is labeled.

67. The antibody of claim 66, wherein the label is selected from the group consisting of:

- (a) an enzyme label;
- (b) a radioisotope; and
- (c) a fluorescent label.

68. A composition comprising the antibody or portion thereof of claim 57 and a carrier.

69. The composition of claim 68, wherein the antibody or portion thereof is a monoclonal antibody.

70. The composition of claim 68, wherein the antibody or portion thereof is a chimeric antibody.

71. The composition of claim 68, wherein the antibody or portion thereof is a humanized antibody.

72. The composition of claim 68, wherein the antibody or portion thereof is a human antibody.

73. The composition of claim 68, wherein the antibody or portion thereof is a single chain antibody.

74. The composition of claim 68, wherein the antibody or portion thereof is a Fab fragment.

75. The composition of claim 68, wherein the antibody or portion thereof is labeled.
76. The composition of claim 75, wherein the label is selected from the group consisting of:
  - (a) an enzyme label;
  - (b) a radioisotope; and
  - (c) a fluorescent label.
77. An isolated cell that produces the antibody of claim 57.
78. A hybridoma that produces the antibody of claim 57.
79. A hybridoma that produces the antibody of claim 59.
80. A method of detecting CSG10 protein in a biological sample comprising:
  - (a) contacting the biological sample with the antibody or portion thereof of claim 57; and
  - (b) detecting the CSG10 protein in the biological sample.
81. The method of claim 80, wherein the antibody is a monoclonal antibody.
82. The method of claim 80, wherein the antibody is a polyclonal antibody.
83. The method of claim 80, wherein the antibody is a chimeric antibody.

84. The method of claim 80, wherein the antibody is a humanized antibody.

85. The method of claim 80, wherein the antibody is a human antibody.

86. The method of claim 80, wherein the antibody is a single chain antibody.

87. The method of claim 80, wherein the antibody is a labeled antibody.

88. The method of claim 87, wherein the label is selected from the group consisting

of:

- (a) an enzyme label;
- (b) a radioisotope; and
- (c) a fluorescent label.